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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,226	09/16/2003	John R. Boehringer	B1256/20003 (11)	2118

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EXAMINER

HAND, MELANIE JO

ART UNIT	PAPER NUMBER
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3761

NOTIFICATION DATE	DELIVERY MODE
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09/22/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary

Application No.

10/663,226

Applicant(s)

BOEHRINGER ET AL.

Examiner

MELANIE J. HAND

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23, 26, 28, 30-33 and 35-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-22, 28, 30-33, 35-38 and 40-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 26, 28, 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 8, 2009 has been entered.

Response to Arguments

2. Applicant's arguments filed July 8, 2009 have been fully considered but they are not persuasive. As to the argument that there is no disclosure nor suggestion in the Svedman reference of a spirally wound cylindrically configured winding of gauze arranged to preferably collapse inward in radial directions, Svedman explicitly discloses a cylindrical piece of fabric or foam. As stated in the prior action in the "Response to Arguments section", a cylindrical piece of material, especially a foam, is by its nature anisotropic with respect to inward collapse upon application of suction force. The same force is being applied across two dimensions of different magnitude. Suction pressure will effect a higher force over a smaller area, thus the contractions or collapse along the two axes of the cylindrical piece of foam will necessarily be different, i.e. the foam cylinder is anisotropic. Svedman fairly suggests a spirally wound piece of material by disclosing a cylinder; spiral winding is simply one way to achieve such a cylindrical shape. Svedman fairly suggests using gauze as a material instead of foam and also suggests spirally wound gauze, because the insertion of spiral windings of gauze in a wound cavity to absorb exudate is a procedure for absorbing exudate that is well known to one of ordinary skill in the art

of wound exudate absorption as well as many other surgical arts. The gauze cylinder suggested by Svedman, like the foam, is also anisotropic and will by its nature contract inward in radial directions upon application of suction pressure.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman (U.S. Patent No. 5,358,494).

With respect to **claim 23**: Svedman teaches a medical device for treating a wound. With regard to (a), the method comprises suction means for applying suction to the wound in the form of a syringe 12. With regard to the limitation "suction means for applying suction to the wound" applicant has disclosed a wall suction device or portable suction pump for applying suction

interpreted herein as the means for applying suction. Svemdan teaches a portable suction pump in the form of syringe 12. (Col. 3, lines 35-39) With regard to the limitation “to facilitate contraction of the wound”, since Svedman teaches a suction means that anticipates the claimed suction means for applying suction, the suction means of Svedman is fully capable of facilitating contraction of the wound. With regard to (b), Svedman teaches an enclosure formed by flexible plate 1. The enclosure of Svedman engages the skin around the wound via adhesive layer 3, thus necessarily maintaining suction on the wound by engaging the skin around the wound. (Fig. 1, Col. 2, lines 34-38) With regard to (c), Svedman teaches an anisotropic wound packing means in the form of a flexible pad 11 for placement in the wound. Pad 11 comprises a cylindrical piece of synthetic fabric which is considered herein to be anisotropic as it is considerably more difficult to contract a roll of fabric via suction in directions that are orthogonal to the direction of suction flow. (Col. 2, lines 56-58) Thus, wound packing 11 has at least one predetermined direction of preferential contraction in response to suction, i.e. the direction parallel to the direction of suction flow. With regard to the limitation “treating a wound by controlling the direction of wound contraction”, Svedman anticipates the limitations of claim 23 as to an anisotropic wound packing and suction means. A wound will necessarily contract only as quickly as the packing filling the wound and removing fluid therefrom is not obstructing the tissue, thus controlling the direction of contraction of the packing by providing an anisotropic packing and applying suction will necessarily control the direction of wound contraction. Thus, the device of Svedman is fully capable of treating a wound by controlling the direction of wound contraction. The phrase “generally spirally wound” is not clearly and explicitly defined in the disclosure by applicant. Thus the claim is given its broadest reasonable interpretation. The generally cylindrical gauze roll suggested by Svedman is considered herein to be generally spirally wound inasmuch as it is formed by winding the fabric at least once to form the cylinder.

Thus, the device of Svedman renders the limitation "said packing comprises at least one generally spirally wound gauze roll" obvious.

Svedman teaches that the packing comprises a cylindrical piece of synthetic fabric. Svedman does not explicitly teach gauze. However it is well known in the art to roll up gauze into a cylindrical configuration and place it in a wound to absorb wound exudate. Therefore, it would be obvious to modify the device of Svedman such that the cylindrical piece of synthetic fabric is a roll of gauze with a reasonable expectation of success to facilitate healing of a wound by absorbing wound exudate.

The packing means fairly suggested by Svedman comprises at least one generally cylindrical gauze roll necessarily having a generally longitudinal axis and radial axes. The longitudinal axis of the roll will necessarily face outwardly from the wound and the radial axes of the roll will necessarily face sides of the wound, regardless of the position in which the roll is oriented within the wound. The motivation to modify the device of Svedman such that the wound packing is a cylindrical piece of gauze is stated *supra* with respect to claim 24.

With respect to **claim 26**: Svedman does not explicitly teach that the packing comprises a plurality of said cylindrical gauze rolls to be disposed with their respective longitudinal axes generally parallel to each other in the wound. However, a plurality of rolls would accomplish the same result as one roll. It would be obvious to one of ordinary skill in the art to modify the device of Svedman such that the packing 11 comprises a plurality of identical gauze rolls identical to the first roll suggested by Svedman with a reasonable expectation of success to provide an effective means of packing a wound. It has been held that the mere duplication of the essential working parts of a device involves only routine skill in the art. *St Regis paper Co. v. Bemis. Co.* 193 USPQ 8 (7th Cir. 1977) Thus the device suggested by Svedman renders the limitation "to

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be disposed with their respective longitudinal axes generally parallel to each other in the wound” obvious. Further this limitation is directed to a method of using the packing that bears little patentable weight herein, as claim 26 is directed to an article.

6. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('494) in view of Zamierowski (U.S. Patent No. 4,969,880).

With respect to **claim 28**: Svedman teaches a portable suction means, “e.g. a syringe”, but does not explicitly a flexible bulb. Zamierowski teaches a wound treatment device comprising an apparatus adapted for manual compression, comprising a flexible bulb 42, with an inlet conduit in the form of suction tube 41 connecting the bulb 42 to the wound enclosure 22 and an outlet conduit 34 connecting the bulb to discharge in the form of pumping medication to wound site 12. Since a flexible bulb and a syringe are both equally effective and equally well known portable means for applying suction, it would be obvious to one of ordinary skill in the art to modify the device of Svedman so as to replace the syringe with a flexible bulb with a reasonable expectation of success to provide an equally effective portable source of suction to allow the device to be used in more various ways and locations.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Primary Examiner, Art Unit 3761